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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,763	10/06/2003	Barry M. Yomtov	17509-0072	8563

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EXAMINER	
SMITH, TERRI L	
ART UNIT	**PAPER NUMBER**
3762	
MAIL DATE	**DELIVERY MODE**
10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,763	YOMTOV ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 20-36* is/are pending in the application.

4a) Of the above claim(s) *4,8-11,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,12-17,20-28 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-6-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 September 2007 has been entered.

Response to Arguments

2. Applicant's arguments, filed on 26 September 2007, with respect to the rejection(s) of claim(s) 1–3, 5–7, 12–17, 20–28, 31–32, 35 and 36 under 35 U.S.C. 102(b) as anticipated by Thompson, Patent Application Publication 2002/0111601, and claim 17 in the alternative under 35 U.S.C. 103(a) as obvious over Thompson, in view of Santini, Jr. et al., U.S. Patent 5,797,898, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Greenberg, U.S. Patent 7,097,775 and Gordon, U.S. Patent 6,349,232, Thompson, Patent Application Publication 2002/0111601, Mann et al., Patent Application Publication U.S. 2002/0055761 and Barrett et al., U.S. Patent 6,587,719.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 3, 5, 7, 17, 20, 21 and 23–26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al., U.S. Patent 7,097,775 and in view of Gordon, U.S. Patent 6,349,232.

6. Regarding claims 1, 2, 7 and 23–26 Greenberg et al. disclose an implantable drug delivery module (e.g., Figs. 1 and 3–6) comprises a plurality of reservoirs, a release system comprises at least one drug (e.g., element 5; column 1, lines 20–24; column 7, lines 5–11),

a plurality of discrete reservoir caps (e.g.; element 9) and means for disintegrating one of the reservoir caps (e.g., column 8, lines 11–29);

a neural electrical stimulator (e.g., column 10, lines 12–17), a signal generator and (e.g., element 335), a least one stimulation electrode (e.g., element 330).

Although Greenberg et al. disclose means for disintegrating one of the reservoir caps, it is not done by electrothermal ablation. Also, Greenberg et al. do not disclose at least one microcontroller and telemetry components. However, Gordon discloses means for disintegrating one of the reservoir caps by electrothermal ablation, at least one microcontroller and telemetry components (e.g., FIGS. 5 and 9–12B, elements 162 and 274-microcontrollers, 160-antenna;

column 8, lines 57–column 9, lines 2 and 18–38) for providing the predictable results of enhancing controlled drug dose delivery to the precise area desired and to optimize the therapeutic effect of treatment.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Greenberg et al. to include electrothermal ablation and at least one microcontroller and telemetry components, as taught by Gordon because both inventions perform controlled drug delivery from an implantable device for providing the predictable results of enhancing controlled drug dose delivery to the precise area desired to optimize the therapeutic effect of treatment.

7. With respect to claims 3, 17, 20, 21 Greenberg discloses a power source (claim 3) (e.g., column 8, lines 21–27); a microchip (claim 17) (e.g., element 1); one sensor (claims 20 and 21) (e.g., column 8, lines 20–27; column 10, lines 58–59 where the electrode is the sensor).

8. Regarding claim 5, Greenberg et al. disclose a hermetically sealed encasement (e.g., FIG. 2; column 5, lines 63–67; column 6, lines 47–67) and a stimulation electrode as described above, but not that it extends a distance from a hermetically sealed encasement. However, Gordon discloses a stimulation electrode extends a distance from a hermetically sealed encasement (e.g., FIG. 11D, element 271) to provide an effective means for providing the predictable results of disintegrating the cell enclosure to allow optimum dispensing of drugs from the reservoirs.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Greenberg et al. to include a stimulation electrode extends a distance from a hermetically sealed encasement, as taught by Gordon

because both inventions provide an effective means for providing the predictable results of disintegrating the cell enclosure to allow optimum dispensing of drugs from the reservoirs.

9. Claims 6, 12–16, 22, 27, 28, 31, 32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al., U.S. Patent 7,097,775 and Gordon, U.S. Patent 6,349,232 and further in view of Thompson, U.S. Patent Application Publication 2002/0111601.

10. Regarding claims 6, 22 and 36, Greenberg et al. and Gordon disclose the essential features of the claimed invention as described above except for a flexible catheter (claims 6 and 36) and a drug is an analgesic (claim 22). However, Thompson discloses a flexible catheter (e.g., Figures 1–4 and 6–9) and a drug is an analgesic (e.g., paragraph [0011], line 5) for providing the predictable results to diversify the places where drug dispensing can be effectively and efficiently administered within the patient and to add variety to the type of drugs that can be administered by the device.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Greenberg et al. and Gordon to include a flexible catheter, as taught by Thompson to diversify, for providing the predictable results to increase and optimize drug dispensing within a patient and to add variety to the type of drugs that can be administered by the device.

11. With respect to claims 12–16, 31, 32 and 35, Greenberg et al. and Gordon disclose the essential features of the claimed invention as described above except for a medical device adapted to treat chronic pain (claims 12 and 31), movement disorders (claims 13 and 32), incontinence (claim 14) and obesity (claim 15) and to control seizures (claims 16 and 35).

However, because incontinence and obesity are intended use claims, Thompson is capable of treating incontinence and obesity since Thompson's device uses several different biologically-active compounds to administer several different therapies.

Thompson discloses a medical device adapted to treat chronic pain (e.g., paragraph [0049], lines 12–14; paragraph [0064], line 21) and movement disorders and to control seizures (e.g., paragraph [0064], lines 11–12 and 24) for providing the predictable results to provide an economic, efficient and safe device that performs a variety of therapies.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Greenberg et al. and Gordon to include a medical device adapted to treat chronic pain, movement disorders, incontinence and obesity and to control seizures, as taught by Thompson for providing the predictable results to provide an economic, efficient and safe device that performs a variety of therapies to improve a patient's quality of life.

12. Regarding claims 27 and 28, Greenberg et al. and Gordon disclose the essential features of the claimed invention as described above except for a drug is released before an electrical neural stimulation and is effective to reduce a stimulation threshold (claim 27) and release of a drug is alternated with delivery of an electrical stimulation (claim 28). However, Thompson discloses a drug is released before an electrical neural stimulation and is effective to reduce a stimulation threshold and release of a drug is alternated with delivery of an electrical stimulation (e.g., paragraphs [0011], lines 5–9 and [0038], lines 4–15) for providing the predictable results to achieve optimum treatment providing maximum comfort to a patient.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Greenberg et al. and Gordon to include a drug is released before an electrical neural stimulation and is effective to reduce a stimulation threshold and release of a drug is alternated with delivery of an electrical stimulation, as taught by Thompson for providing the predictable results to achieve optimum treatment providing maximum comfort to a patient.

13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al., U.S. Patent 7,097,775, Gordon, U.S. Patent 6,349,232 and Thompson, U.S. Patent Application Publication 2002/0111601 and further in view of Mann et al., Patent Application Publication U.S. 2002/0055761.

Greenberg et al., Gordon and Thompson disclose the essential features of the claimed invention as described above except for a method used to treat incontinence in a patient. However, Mann discloses a medical device for treating incontinence in a patient (e.g. paragraph [0002]) for providing the predictable results to reduce or eliminate the incidence of unintentional episodes of bladder emptying and to improve the long-term health of the urinary system by increasing bladder capacity and thus, the time period between emptying.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Greenberg et al., Gordon and Thompson for providing the predictable results to include a method used to treat incontinence in a patient, as taught by Mann to improve the health of a patient's urinary system.

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al., U.S. Patent 7,097,775, Gordon, U.S. Patent 6,349,232 and Thompson, U.S. Patent Application Publication 2002/0111601 and further in view of Barrett et al., U.S. Patent 6,587,719.

Greenberg et al., Gordon and Thompson disclose the essential features of the claimed invention as described above except for a method used to treat obesity in a patient. However, Barrett discloses a medical device for treating obesity in a patient (e.g. sole Figure; column 8, line 58) for providing the predictable results to produce a sensation of satiety in the patient to effectively control compulsive overeating.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Greenberg et al., Gordon and Thompson for providing the predictable results to include a method used to treat obesity in a patient, as taught by Barrett to improve a patient's eating habits.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
October 5, 2007
5 October 2007

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/9/7